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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874

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EXAMINER	
MOULTON, ELIZABETH ROSE	
ART UNIT	PAPER NUMBER
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/711,648	PONZI ET AL.	
	Examiner	Art Unit	
	ELIZABETH R. MOULTON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23-28,30-35,39 and 44-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,23-28,30-35,39 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 48-50 are objected to because of the following informalities: these claim have the wrong status identifiers. They should be identified as previously presented, not new. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5-20,23-25,27,28,30-35 and 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over ABELE (US #5,403,311) in view of West et al (US 5,318,525) and further in view of Langer et al (US 6,004,295)

Regarding claim 1, Abele teaches "An injection catheter comprising: a catheter body (28) comprising a flexible tubing (30) having proximal and distal ends and at least one lumen (not labeled, Col 5 lines 47-65) there through; a tip section (e.g. 52) having a longitudinal axis and comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body (Fig 1, Fig 6); a needle control handle (17) at the proximal end of the catheter body; an injection needle (24) extending through the tip section, catheter body, and

needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that upon suitable manipulation of the needle control handle the distal end of the injection needle can extend distally beyond the distal end of the tip section in a direction along the longitudinal axis of the tip section to penetrate tissue generally facing a distal face of the tip section (Fig 1); an electrode lead wire having a first end electrically connected to the injection needle (26) and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (16), with a penetration monitoring electrode (26) mounted on the injection needle." See also Col 3, lines 25-52, and Col 4 lines 19-29, and Col 5 lines 53-55. As to the plastic tubing, Abele discloses that the injection needle comprises plastic tubing (34) which is a plastic (polyamide) insulating sheath. Fig 2.

Abele does not teach a puller wire and deflection control handle for controlling the deflection of the tip section or the penetration monitoring electrode fixedly mounted on the needle tip. West teaches a catheter with puller wire (44) connected to the distal end of a tip section of a catheter (16) and connected to a deflection control handle (24) which controls deflection of the catheter tip (Fig 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the puller wires of West with the catheter of Abele in order to controllably steer the catheter through the vasculature to the desired treatment location in the body.

Langer teaches an injection needle which slides in and out of a catheter (Fig 4A-4C) which may have a penetration monitoring electrode (80, Fig 8A) fixedly mounted on the needle. See Col 8 lines 20-35. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the fixed penetration monitoring electrode of Langer with the catheter of Abele and West as an alternate design choice for penetration monitoring. Simple substitution of one device for another is within the skill of an ordinary worker in the art.

Regarding claims 9 and 11, Abele teaches the limitations of claim 1 above, with the substitution and/or addition of an electrode mounted on the injection needle being electrically isolated for the injection needle. (Col 8 lines 60-Col 9 line 5).

Regarding claim 23, the claim recites the same limitations as claim 1 without explicitly defining the tip section. Examiner takes the proximal end of the catheter to be equivalent to the tip section of claim 1; therefore claim 23 is rejected under Abele.

Regarding claims 2,3,24, and 25, the electrode can be mounted at the distal or proximal end of the injection needle (52, 56)

Regarding claims 5,6,27 and 28, Examiner takes the protective tube to be the cross-braided stainless steel filaments 30.

Regarding claims 7, 14, 19, and 46, Abele teaches the use of at least one additional electrode (Fig 10, 72 and 74)

Regarding claim 8, Abele teaches that the tip of the needle can be an electrode (Col 6 line 15)

Regarding claim 10, Abele teaches the use of a ring electrode (e.g. 26, Col 5 line 51)

Regarding the method claims 12, 13, 15, 17, 18, 20, 30-35, 44, 45, and 47, Abele describes various potential methods of use, disclosing all of the claimed methods. See "Summary of the Invention" and "Description of Preferred Embodiments."

group angiogenesis activators, angiogenesis inhibitors, and antiarrythmic drugs."

As to claim 16, Abele teaches the limitations of claims 12 and 1, but only specifies the use of a "vasoconstrictor, sclerotic, topical anesthetic, or heat responsive drug."

Because Abele's catheter and the disclosed invention are both designed to be used to abate tissue in the heart, the selection of one drug over another is a matter of obvious design choice.

3. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele, Langer and West as applied to claims 1 and 23 above, and further in view of COSMAN (US #4,966,597).

Abele and West teach the limitations of a catheter for introduction into cardiac tissues, but does not teach the use of a pair of copper and constantan wires used as a thermocouple probe.

Cosman teaches the use of a thermocouple composed of copper and constantan wires (elements 1 and 5) in a cardiac catheter (Fig 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the electrode thermocouple probe of Cosman with the

cardiac catheter of Abele and West is order to facilitate "true surface temperature recording with fast response" (Cosman Abstract)

Response to Arguments

Applicant's arguments filed 22 March 2010 have been fully considered but they are not persuasive. Applicant argues that Abele does not teach an isolated electrode. As referenced in the previous office action, Abele teaches at Col 8 line 60: Referring now to FIG. 6, a distal end of a catheter 50 includes a rounded end portion 52 secured to the end of a catheter shaft 54. Rounded end portion 52 is fabricated from a refractory material such as ceramic and is entirely coated with a conductive metal, such as gold to provide a first electrode of the catheter. A projectable, tissue-penetrable needle tip electrode 56, representing a second **electrode isolated from the gold coated first electrode**, extends coaxially from end portion 52 which when coupled to a RF electrocoagulation current generator provides a bipolar coagulation catheter. It unclear why applicant was reviewing the teachings of Langer regarding this feature. The rejection is maintained.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on part-time R and F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767